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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kathleen M. Miller et al.  
 Application No.: 10/789,398  
 Date Filed: 02/27/2004  
 Title: IMPLANTABLE OR INSERTABLE MEDICAL DEVICE RESISTANT TO MICROBIAL GROWTH AND BIOFILM FORMATION  
 Group Art Unit.: 3738  
 Confirmation No.: 4925  
 Atty. Docket No.: 98-P0151US2

## INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop Amendment  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

## SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a.  A legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b.  Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial NumberU.S. Filing DateII. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a.  Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b.  A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c.  The following additional information is provided for the Examiner's consideration:

III.  CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.Filing DateArt Unit

FEES

- IV.  THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b): (check one box)
- a. within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
  - b. within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
  - c. before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
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- V.  THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c): (check one box)  
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
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on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
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- VII.  STATEMENT UNDER 37 C.F.R. §1.97(e) (check only one box, if applicable)  
The undersigned hereby states that
- a. each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
  - b. no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
  - c. some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. PAYMENT OF FEES
- A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
  - Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).
  - If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
  - Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



Keum J. Park  
Attorney for Applicant(s)  
Reg. No. 42,059  
Tel.: 908-518-7700  
FAX: 908-518-7795

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- PTO/SB/08
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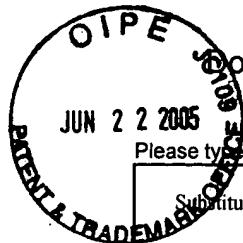
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~~Docket No.: 98-P0151US2~~

JUN 22 2005

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**Substitute for form 1449A/PTO**

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Application Number</b> 10/789,398 <b>Filing Date</b> 02/27/2004 <b>First Named Inventor</b> Kathleen M. Miller <b>Group Art Unit</b> 3738 <b>Confirmation No.</b> 4925 <b>Examiner Name</b> Unassigned	
Sheet	1	of	3	<b>Attorney Docket Number</b> 98-P0151US2	

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Publication		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
	1.	2004/0249441 A1	623/1.15	Miller et al.	12/09/2004
	2.	2004/0166102 A1	424/93.45	Darouiche et al.	08/26/2004
	3.	2004/0166094 A1	424/93.4	Darouiche et al.	08/26/2004
	4.	2003/0224033 A1	424/423	Li et al.	12/04/2003
	5.	2003/0199993 A1	623/23.75	Gellman et al.	10/23/2003
	6.	2003/0153983 A1	623/23.7	Miller et al.	08/14/2003
	7.	2003/0018306 A1	604/265	Bucay-Couto et al.	01/23/2003
	8.	2002/0031601 A1	427/2.1	Darouiche et al.	03/14/2002
	9.	2004/0208908 A1	424/423	Modak et al.	10/21/2004
	10.	2003/0203991 A1	523/334	Schottman et al.	10/30/2003
	11.	2003/0078242 A1	514/150	Raad et al.	04/24/2003
	12.	2003/0024534 A1	128/846	Silvestri et al.	02/06/2003

Examiner Signature  
Date Considered

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
Sheet	2	of	3	Application Number	10/789,398
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				Group Art Unit	3738
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				Examiner Name	Unassigned
				Attorney Docket Number	98-P0151US2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	1.	Percuflex® Tail Plus™Tapered Ureteral Stent. Boston Scientific. Urology. <a href="http://www.bostonscientific.com/med_specialty/deviceDetail.jhtml?task=tskBasicDevice.jhtml&amp;s.2/24/2004 download.">http://www.bostonscientific.com/med_specialty/deviceDetail.jhtml?task=tskBasicDevice.jhtml&amp;s.2/24/2004 download.</a>			
	2.	H.N. BHARGAVA ET AL., "Triclosan: Applications and Safety," <i>American Journal of Infection Control</i> , vol. 24(3), June 1996, pp. 209-218.			
	3.	RHONDA D. JONES ET AL., "Triclosan: A Review of Effectiveness and Safety in Health Care Settings," <i>American Journal of Infection Control</i> , vol. 28(2), Apr. 2000, pp. 184-196.			
	4.	J. REGÓS ET AL., "Antimicrobial Spectrum of Triclosan, a Broad-Spectrum Antimicrobial Agent for Topical Application. II. Comparison with Some Other Antimicrobial Agents," <i>Dermatologica</i> , vol. 158, 1979, pp. 72-79.			
	5.	STEPHEN ROTHENBURGER ET AL., "In Vitro Antimicrobial Evaluation of Coated VICRYL* Plus Antibacterial Suture (Coated Polyglactin 910 with Triclosan) Using Zone of Inhibition Assays," <i>Surgical Infections</i> , vol. 3, supplement, 2002, pp. S-79-S87.			
	6.	EDWARD S. WONG ET AL., Guideline for Prevention of Catheter-associated Urinary Tract Infections. <a href="http://www.cdc.gov">http://www.cdc.gov</a> . n.d. but before the date of this application.			
	7.	ALLAN RONALD, "The Etiology of Urinary Tract Infection: Traditional and Emerging Pathogens," <i>Dis. Mon.</i> , vol. 49, 2003, pp. 71-82.			
	8.	ALAIN MEYRIER, Urinary Tract Infections, Vol. II, Chapter 7 of <i>The Schrier Atlas of Diseases of the Kidney</i> , ed. Robert W. Schrier, 1999.			
	9.	DONALD P. GRIFFITH ET AL., "Urease: The Primary Cause of Infection-Induced Kidney Stones," <i>Investigative Urology</i> , vol. 13(5), March 1976, pp. 346-350.			
	10.	D.J. STICKLER ET AL., "Control of Encrustation and Blockage of Foley Catheters," <i>The Lancet</i> , vol. 361, April 26, 2003, pp. 1435-1437.			

Examiner Signature	Date Considered
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<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English Language Translation is attached.

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				First Named Inventor	Kathleen M. Miller
				Group Art Unit	3738
				Confirmation No.	4925
				Examiner Name	Unassigned
				Attorney Docket Number	98-P0151US2

<b>OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	11.	Ciba Specialty Chemicals. Ciba® IRGASAN® DP 300, Ciba® IRGACARE® MP Antimicrobials. Toxicological and ecological data; Official registrations. Jan. 2003. 16 pages.			
	12.	Ciba Specialty Chemicals. Ciba® IRGASAN® DP 300, Ciba®IRGACARE® MP. Antimicrobial active ingredient for personal care products. 2001. 16 pages.			

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